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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,797	04/16/2004	Robert B. Fick	P0957R1C1	1468

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,797	FICK ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 40-50* is/are pending in the application.

4a) Of the above claim(s) *6,8,44-48 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-16,18,40-43 and 49* is/are rejected.

7)☒ Claim(s) *17 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michael Szperka at Group Art Unit 1644.

Applicant's election of the specie "a steroid" for the genus of adjuvants in the reply filed on November 9, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 44-48 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse as explained above in the reply filed on November 9, 2006. Note that the search has been extended beyond the elected adjuvant species of steroid.

Claims 1-19 and 40-50 are pending in this application.

Claims 6, 8, 44-48, and 50 are withdrawn for the reasons of record or as discussed above.

Claims 1-5, 7, 9-19, 40-43, and 49 are under examination in the instant office action as they read on a method of treating late asthmatic response (LAR) by administering a humanized anti-IgE antibody.

Priority

2. The benefit claim filed on June 14, 2005 was not entered because the required reference was not timely filed within the time period set forth in 37 CFR 1.78(a)(2) or (a)(5). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires the benefit under 35 U.S.C. 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Further, a review of the earliest claimed priority document, PCT/US92/06860, and the other documents in section (2) of the priority claim submitted June 14, 2005 do not appear to fully disclose the instant claimed methods. Specifically, while these documents do teach methods of administering humanized anti-IgE antibodies to treat allergic diseases including asthma, it does not appear that these documents disclose a method of specifically treating LAR.

In view of all of the above, the priority date assigned to the claims of the instant application is that of provisional application 60/029,182 filed on July 27, 1995. It is noted that utility application 08/508,014 filed July 27, 1995 was converted to provisional application 60/029,182, and that the text and drawings of the specifications of 60/029,182, 08/686,902, and 10/826,797 appear to be identical.

Information Disclosure Statement

3. Applicant's IDS received July 30, 2004 is acknowledged and has been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 40-43 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the claims appear to define members of a Markush grouping as "adjuvants." The art recognized definition of an adjuvant is a substance that enhances the immune response to an antigen (Janeway et al., Immunobiology, third edition, 1997, page G1). The substances in the Markush grouping are all well known agents that are used in methods of decreasing immune responses, such as in treatments for asthma, as taught in WO 95/01175 A1 (see entire document, particularly pages 1 and 2). Since these agents are known to decrease immune responses such as those in asthma, it is not clear how they can be considered adjuvants. Applicant is requested to clarify this issue or remove the term "adjuvant" from the instant claims.

Claim 40 is also indefinite in the recitation of *beclomethasone, diproprionate* since as is taught by Cockcroft et al. (of record as reference 227 on the IDS received 7/30/04, see entire document) beclomethasone diproprionate is a single compound. Appropriate clarification as to the precise nature of the chemicals being recited in the instant claim is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 40-43 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has recited a method of administering an anti-IgE antibody with an adjuvant selected from a Markush grouping. The claims indicate that the adjuvant can be administered before, after, or in combination with administration of the anti-IgE antibody. None of the Markush members appear to be disclosed as "adjuvants" in the instant specification. They Markush members themselves do appear to be disclosed in lines 30-34 of page 20. This disclosure indicates that the members of the Markush grouping can be combined with the administered anti-IgE antibody, but there does not appear to be any disclosure that these "adjuvants" can be administered at any time other than concurrently with the anti-IgE antibody. Therefore, it appears that the indicated claims contain new matter with regard to the timing of administration and the characterization of the agents as "adjuvants". In response to this rejection, applicant is required to either cancel the new matter or point out where support for these limitations can be found.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 40 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Jardieu et al. (WO 93/04173, of record as document 35 on the IDS received 7/30/04, see entire document).

Jardieu et al. teach methods of treating allergic disorders including asthma by administering humanized anti-IgE antibodies (see entire document, particularly the abstract, lines 8-11 of page 1, and lines 30-38 of page 6). These antibodies are further disclosed as being administered in combination with other known agents to treat allergies with antihistamines being taught as a specific agent (see particularly lines 19-24 of page 43).

Therefore, the prior art anticipates the instant invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 5, 7, 9-12, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jardieu et al. (WO 93/04173, of record as document 35 on the IDS received 7/30/04, see entire document) in view of Larsen et al (of record as document 227 on the IDS received 7/30/04, see entire document).

Jardieu et al. teach methods of administering humanized anti-IgE antibodies for therapy and prophylaxis of allergic and other IgE-mediated disorders (see entire document, particularly the abstract and lines 30-34 of page 6). Note that a prophylactic dose would necessarily be given prior to the onset of symptoms, while a therapeutic dose would be given subsequent to the development of symptoms. One particular anti-IgE antibody taught by Jardieu et al. is humanized e25, the same antibody used in the working examples of the instant application, which is taught as binding soluble IgE but not IgE bound to FcεRI present on cells such as basophils (see particularly lines 7-17 of page 7). It is also disclosed that these antibodies are to be administered with other known anti-allergic compounds including antihistamines (see particularly lines 19-24 of page 43). Anti-IgE antibodies are taught as being administered at concentrations that are greatly in excess of serum IgE such that the antibodies effectively prevent binding of endogenous IgE to its receptors (see particularly the paragraph that spans pages 42

and 43). These teachings differ from the instant claimed method in that while they teach methods for the therapy and prophylaxis of allergic and other IgE-mediated disorders and teach that IgE mediates asthma (see particularly lines 8-11 of page 1), these teachings do not specify that the late asthmatic response (LAR) is an IgE mediated disorder.

Larsen et al. teach that LAR is an IgE mediated disorder because LAR is dependent upon the presence of antigen-specific IgE (see entire document, particularly the last sentence of the upper paragraph of page 253).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer anti-IgE antibodies to treat LAR. Motivation to do so comes from the teachings of Larsen et al. that LAR is an IgE-mediated condition that is dependent upon the presence of antigen-specific IgE and the teachings of Jardieu et al. that anti-IgE antibodies are to be administered for treatment and prophylaxis of IgE-mediated disorders. Note that while these teachings do indicate that administering anti-IgE antibodies reduces free IgE concentration (see particularly lines 30-38 of page 1 of Jardieu et al.), they do not teach the specific value of less than 40 ng/mL. However, it is inherent that administration of anti-IgE antibodies would result in such a decrease, especially given that the humanized antibody disclosed by Jardieu et al. and the humanized antibody used in the working examples of the instant invention is the same antibody.

12. Claims 2, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jardieu et al. (WO 93/04173, of record as document 35 on the IDS received 7/30/04, see entire document) in view of Larsen et al (of record as document 227 on the IDS received 7/30/04, see entire document) as applied to claims 1, 5, 7, 9-12, 16, and 18 above, and further in view of Rup et al. (US Patent No. 4,940,782, of record as document 4 on the IDS received 7/30/04, see entire document).

The teachings of Jardieu et al. and Larsen et al. have been discussed above. These teachings differ from the instant invention in that they do not explicitly teach the repeated administration of anti-IgE antibodies in formulations comprising buffers and other additives.

Rup et al. teach methods of administering anti-IgE antibodies. These antibodies are taught as being administered at dosages that can readily be determined by one of skill in the art, with such dosages being repeated daily or for a period of time (see particularly lines 50-65 of column 5). The anti-IgE antibodies are administered in formulations comprising buffers and preservatives (see entire document, particularly lines 3-18 of column 6. These formulations offer the advantage of allowing the anti-IgE antibodies to be administered by a variety of modes such as parenterally and intravenously.

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to administer the anti-IgE antibodies taught by Jardieu et al. to treat LAR as taught by Jardieu et al. and Larsen et al. in formulations comprising buffers and other ingredients as taught by Rup et al. to gain the advantage of

administering the anti-IgE antibodies by a variety of modes such as parenterally and intravenously. Note that freeze-drying of the anti-IgE antibody prior to its reconstitution in a pharmaceutical composition would not materially alter the structure or therapeutic properties of the antibody actually administered in such a composition, and as such dependent claim 15 has been included in this rejection. Note also that the claims do not require the loading and maintenance doses to differ in concentration.

13. Claims 3, 4, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jardieu et al. (WO 93/04173, of record as document 35 on the IDS received 7/30/04, see entire document) in view of Larsen et al (of record as document 227 on the IDS received 7/30/04, see entire document) and in view of Rup et al. (US Patent No. 4,940,782, of record as document 4 on the IDS received 7/30/04, see entire document) as applied to claims 1, 2, 5, 7, 9-12, 14-16, and 18 above, and further in view of Jardieu et al. (Jardieu2, US Patent No. 5,622,700, see entire document).

The teachings of Jardieu et al., Larsen et al., and Rup et al. have been discussed above. These teachings differ from the instant invention in that they do not explicitly teach the administration of anti-IgE on a weekly or biweekly basis, or that an administered loading dose is greater than a maintenance dose.

Jardieu2 teach that the administration of antibodies to treat chronic disorders, such as asthma, is to be done by administering the antibodies in an initial (i.e. loading) dose followed by maintenance dosing, wherein the maintenance doses are lower than the initial dose (see entire document, particularly lines 3-14 and 31-44 of column 7).

The maintenance doses are taught as being administered either weekly or biweekly (see particularly from line 24 of column 12 to line 27 of column 13). Such as dosing regimen offers the advantage of providing the most efficacious therapeutic results (see particularly lines 1-12 of column 13).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to treat the IgE-mediated disease LAR as taught by Larson et al. by administering the humanized anti-IgE antibodies taught by Jardieu et al. in the formulations taught by Rup et al. using the dosage timings and amounts disclosed by Jardieu2 in order to gain the advantage of the most therapeutically efficacious manner of administering the anti-IgE antibody.

14. Claims 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jardieu et al. (WO 93/04173, of record as document 35 on the IDS received 7/30/04, see entire document) in view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740, of record as document 67 on the IDS received 7/30/04, see entire document).

The teachings of Jardieu et al. have been discussed above. These teachings differ from the instant claimed invention in that while they teach the administration of anti-IgE antibodies to treat asthma, teach that anti-IgE antibodies are to be administered in combination with additional therapeutic agents commonly used for treatment of allergies, and give a non-limiting example of such an agent as being antihistamines, they do not teach administration with the elected species of steroids.

Cockcroft et al. teach that administration of multiple anti-asthmatic agents offer an advantage because administration of only a single agent is often inadequate to clinically treat symptoms (see entire document, particularly the abstract and discussion section). It is further taught that steroids are desirable for combination therapy with anti-asthmatic agents since they have the advantageous property of being able to be administered prophylactically (see particularly the last sentence of the abstract and the last paragraph of the discussion on page 739).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to substitute steroids as taught by Cockcroft et al. for antihistamines in compositions comprising anti-IgE antibodies as taught by Jardieu et al. to gain the advantage of using an agent known to be effective in treating asthma that can be administered prophylactically.

15. Claims 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman et al. (EP 0 589 840 A1, of record as document 25 on the IDS received 7/30/04, see entire document) in view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740, of record as document 67 on the IDS received 7/30/04, see entire document).

Hardman et al. teach methods of administering anti-IgE antibodies to treat allergic asthma (see entire document, particularly the abstract, lines 32-58 of page 15, and most particularly the sentence that spans pages 15 and 16). These teachings differ

from the claimed invention in that they do not explicitly teach the administration of anti-IgE antibodies with additional active ingredients such as steroids.

Cockcroft et al. teach that administration of multiple anti-asthmatic agents offer an advantage because administration of only a single agent is often inadequate to clinically treat symptoms (see entire document, particularly the abstract and discussion section). It is further taught that steroids are desirable for combination therapy with anti-asthmatic agents since they have the advantageous property of being able to be administered prophylactically (see particularly the last sentence of the abstract and the last paragraph of the discussion on page 739).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to treat allergic asthma by administering the anti-IgE antibodies of Hardman et al. in combination with steroids as taught by Cockcroft et al. to gain the advantage of increased therapeutic efficacy since administration of a single anti-asthmatic agent is often therapeutically inadequate as was taught by Cockcroft et al.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 5, 7, 9-10, and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,699,472 in view of Larsen et al. (of record as document 227 on the IDS received 7/30/04, see entire document).

The claims of '472 recite a method of treating an allergic condition by administering a humanized anti-IgE antibody, and specifically recite the allergic condition asthma. The specification teaches that IgE mediates allergic disorders including asthma (see particularly lines 23-25 of column 1 and lines 38-52 of column 4), but it does not specify that LAR is an IgE-mediated allergic disorder. Note that the patented claims are more narrowly drawn in that they recite anti-IgE antibodies rather than the more generic term IgE antagonists.

Larsen et al. teach that LAR is an IgE mediated disorder because LAR is dependent upon the presence of antigen-specific IgE (see entire document, particularly the last sentence of the upper paragraph of page 253).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer anti-IgE antibodies to treat LAR. Motivation to do so comes from the teachings of Larsen et al. that LAR is an IgE-mediated condition that is dependent upon the presence of antigen-specific IgE and the claims of '472 which teach treatment of allergic disorders by administering anti-IgE antibodies.

18. Claims 1, 5, 7, and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,685,939 in view of Larsen et al. (of record as document 227 on the IDS received 7/30/04, see entire document).

The claims of '939 recite a method inhibiting the onset of an allergic condition by administering a humanized anti-IgE antibody, and specifically recite the allergic condition asthma. The specification teaches that IgE mediates allergic disorders including asthma (see particularly lines 23-25 of column 1 and lines 38-52 of column 4), but it does not specify that LAR is an IgE-mediated allergic disorder. Note that the antibody must be administered prior to the onset of asthma symptoms in order to effectively inhibit the onset of asthma. Also note that the patented claims are more narrowly drawn in that they recite anti-IgE antibodies rather than the more generic term IgE antagonists.

Larsen et al. teach that LAR is an IgE mediated disorder because LAR is dependent upon the presence of antigen-specific IgE (see entire document, particularly the last sentence of the upper paragraph of page 253).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer anti-IgE antibodies to treat LAR. Motivation to do so comes from the teachings of Larsen et al. that LAR is an IgE-mediated condition that is dependent upon the presence of antigen-specific IgE and the claims of '939 which teach inhibiting the onset of asthma and other allergic disorders by administering anti-IgE antibodies.

19. Claims 40 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,699,472 in view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740, of record as document 67 on the IDS received 7/30/04, see entire document).

The claims of '472 recite a method of treating asthma by administering a humanized anti-IgE antibody. They differ from the instant claimed invention in that additional anti-asthmatic compounds are not recited as being concordantly administered, although they are narrower in scope since they recite anti-IgE antibodies rather than the more generic term IgE antagonists.

Cockcroft et al. teach that administration of multiple anti-asthmatic agents offer an advantage because administration of only a single agent is often inadequate to clinically treat symptoms (see entire document, particularly the abstract and discussion

section). It is further taught that steroids are desirable for combination therapy with anti-asthmatic agents since they have the advantageous property of being able to be administered prophylactically (see particularly the last sentence of the abstract and the last paragraph of the discussion on page 739).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to treat allergic asthma by administering the humanized anti-IgE antibodies recited in the methods of the '472 patent in combination with steroids as taught by Cockcroft et al. to gain the advantage of increased therapeutic efficacy since administration of a single anti-asthmatic agent is often therapeutically inadequate as was taught by Cockcroft et al.

20. Claims 40 and 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, and 6 of copending Application No. 11/013,966 in view of view of Cockcroft et al. (J. Allergy Clin. Immunol. 1987, 79:734-740, of record as document 67 on the IDS received 7/30/04, see entire document).

The claims of application 11/013,966 teach a method of treating the IgE-mediated disorder allergic asthma by administering specific humanized anti-IgE antibodies. These claims differ from the instant claimed invention that that they do not recite that the anti-IgE antibodies are to be administered with an additional active ingredient such as a steroid, but are narrower in scope since they recite anti-IgE antibodies rather than the more generic term IgE antagonists.

Cockcroft et al. teach that administration of multiple anti-asthmatic agents offer an advantage because administration of only a single agent is often inadequate to clinically treat symptoms (see entire document, particularly the abstract and discussion section). It is further taught that steroids are desirable for combination therapy with anti-asthmatic agents since they have the advantageous property of being able to be administered prophylactically (see particularly the last sentence of the abstract and the last paragraph of the discussion on page 739).

Therefore, a person of ordinary skill in the art at the time the invention was made would have been motivated to treat allergic asthma by administering the humanized anti-IgE antibodies recited in the claims of copending application 11/013,966 in combination with steroids as taught by Cockcroft et al. to gain the advantage of increased therapeutic efficacy since administration of a single anti-asthmatic agent is often therapeutically inadequate as was taught by Cockcroft et al.

This is a provisional obviousness-type double patenting rejection.

21. Claims 1, 5, 7, 9, 10, 12, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 5, and 6 of copending Application No. 11/013,966 in view of view of Larsen et al. (of record as document 227 on the IDS received 7/30/04, see entire document).

The claims of application 11/013,966 teach a method of treating IgE-mediated disorders by administering anti-IgE antibodies, including humanized antibodies, in formulations comprising buffers. A specifically recited humanized antibody,

rhuMAbE25, is taught as binding free IgE but not binding FcεRI-bound IgE. These claims differ from the instant claimed invention that that they do not recite that the IgE-mediated disorder is LAR, but are more narrowly constructed than the instant claims in that they recite anti-IgE antibodies rather tan the more generic term IgE antagonists.

Larsen et al. teach that LAR is an IgE mediated disorder because LAR is dependent upon the presence of antigen-specific IgE (see entire document, particularly the last sentence of the upper paragraph of page 253).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer anti-IgE antibodies to treat LAR. Motivation to do so comes from the teachings of Larsen et al. that LAR is an IgE-mediated condition that is dependent upon the presence of antigen-specific IgE and the claims of copending application 11/013,966 which teach treatment of IgE-mediated disorders by administering anti-IgE antibodies.

This is a provisional obviousness-type double patenting rejection.

22. Claims 1, 5, 12, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37, 44-46, and 49 of copending Application No. 09/705,457 in view of view of Larsen et al. (of record as document 227 on the IDS received 7/30/04, see entire document).

The claims of application 09/705,457 recite a method of treating IgE-mediated disorders by administering anti-IgE antibodies, in formulations comprising buffers. The anti-IgE antibodies that are administered are recited as having been lyophilized prior to

reconstitution for administration. These claims differ from the instant claimed invention that that they do not recite that the IgE-mediated disorder is LAR. Note that the copending claims are more narrowly drawn in that they recite anti-IgE antibodies rather than the more generic term IgE antagonists.

Larsen et al. teach that LAR is an IgE mediated disorder because LAR is dependent upon the presence of antigen-specific IgE (see entire document, particularly the last sentence of the upper paragraph of page 253).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer anti-IgE antibodies to treat LAR. Motivation to do so comes from the teachings of Larsen et al. that LAR is an IgE-mediated condition that is dependent upon the presence of antigen-specific IgE and the claims of copending application 09/705,457 which teach treatment of IgE-mediated disorders by administering anti-IgE antibodies.

This is a provisional obviousness-type double patenting rejection.

Claim Objections

23. Claim 1 is objected to because it recites FceRI rather than FcεRI.

Claims 17 and 19 are objected to because the recitation of mg/kg/week/baseline IgE IU/ml makes the claim less clear than what is disclosed in the specification. It is suggested that the claims be amended to recite "about 0.001 to 0.01 mg/kg/week IgE antagonist for every IU/ml baseline IgE in the patient's serum" as can be found in lines 10-14 of page 6, or some other wording supported by the specification that makes clear

the relationship between all of the various units currently recited in an abbreviated form in the instant claims. It should also be noted that such low doses of anti-IgE antibodies are clinically effective as evidenced by the teachings of Fick (Current Opinion in Pulmonary Medicine, 1999, 5:76-80, see entire document, particularly the left column of page 79).

24. No claims are allowable.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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